

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER ASZD-P01-881 U.S. APPLICATION NO. (If known, see 35 CFR 1.5) <div style="font-size: 24pt; font-weight: bold; text-align: center;">10/533869</div>
INTERNATIONAL APPLICATION NO. PCT/SE2003/001738	INTERNATIONAL FILING DATE 11 November 2003	PRIORITY DATE CLAIMED 12 November 2002
TITLE OF INVENTION AN AQUEOUS PHARMACEUTICAL FORMULATION COMPRISING THE THROMBIN INHIBITOR MELAGATRAN AND USE OF THE FORMULATION IN THE MANUFACTURE		
APPLICANT(S) FOR DO/EO/US Edman et al.		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☒ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☒ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Copy of International Preliminary Examination Report from PCT/SE2003/001738
 Copy of International Search Report from PCT/SE2003/001738
 Return Receipt Postcard

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.53) 10/533869		INTERNATIONAL APPLICATION NO. PCT/SE2003/001738		ATTORNEY'S DOCKET NUMBER ASZD-P01-881	
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input checked="" type="checkbox"/> Basic national fee\$300				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee					
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)\$100					
All other situations\$200				\$ 200.00	
23. <input checked="" type="checkbox"/> Search fee					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority\$100					
International Search Report prepared and provided to the Office\$400					
All other situations\$500				\$ 500.00	
TOTAL OF 21, 22 and 23 =				\$ 1,000.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
9 - 100 =	/50 =		x \$250.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	3 - 20 =		x	\$ 0.00	
Independent claims	3 - 3 =		x	\$ 0.00	
MULTIPLE DEPENDENT CLAIM(s) (if applicable)				+	\$
TOTAL OF ABOVE CALCULATIONS =				\$ 1,000.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$	
SUBTOTAL =				\$ 1,000.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				+	\$
TOTAL NATIONAL FEE =				\$ 1,000.00	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$ 40.00
TOTAL FEES ENCLOSED =				\$ 1,040.00	
				Amount to be refunded:	\$
				Amount to be charged:	\$
a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.					
b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>18-1945</u> in the amount of \$ <u>1,040.00</u> to cover the above fees.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>18-1945</u> .					
d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Patricia Granahan, Sc.D. ROPES & GRAY LLP One International Place Boston, Massachusetts 02110-2624 (617) 951-7449 CUSTOMER NUMBER: 28120			SIGNATURE: <u>David P. Halstead, Ph.D.</u> NAME _____ 44,735 REGISTRATION NUMBER		

10/533869

JCO6 Rec PCT/PTO 05 MAY 2005

Application No. (if known): Not Yet Assigned

Attorney Docket No.: ASZD-P01-881

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV520562595US in an envelope addressed to:

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Mary Jane DiPalma

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Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Transmittal Letter to the United States Designated-Elected Office (2 pages)

Preliminary Amendment (5 pages)

Copy of PCT/SE2003/001738 with cover page (10 pages)

Copy of International Preliminary Examination Report (5 pages)

Application Data Sheet (3 pages)

Oath or declaration of the inventor(s) (2 pages)

IDS and PTO Form SB/08 (3 pages)

Copy of International Search Report from PCT/SE2003/001738 (6 pages)

Recordation Form Cover Sheet and Assignment (3 pages)

Charge \$1,040.00 to deposit account 18-1945

This Certificate of Express Mail (1 page)

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